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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/523,532	03/10/00	BARRY D	9045-2CT

020792 LM02/0707
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EXAMINER	
HAYES, J	
ART UNIT	**PAPER NUMBER**
2761	3

DATE MAILED: 07/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/523,532	Applicant(s) BARRY ET AL.	
	Examiner John W Hayes	Art Unit 2761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *10 March 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *5,28 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-4,6-27,29-50 and 52-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4, 6-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6-22 of U.S. Patent No. 6,081,786. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the limitations of claims 1-4 and 6-23 in the instant application are claimed in the patent, with the exception of selection of a therapeutic treatment regimen for a patient with a chronic known disease, providing patient information including prior therapeutic treatment regimen information for the chronic known disease or medical condition, and generating a listing of available therapeutic treatment regimens based on the patient information and the first knowledge base. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention that the method could be applied to chronic diseases as well as any other type of medical condition where therapeutic treatments are applied to treat the symptoms. Also, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to include prior therapeutic treatment regimen information for the patient in order to understand the history of the patient so that changes in the regimen can be proposed that would potentially improve the health of the patient, especially if the prior treatment regimen has not been successful. This is a practice that has been typically performed by most physicians for many years. Furthermore, it would also have been

obvious to one of ordinary skill in the art at the time of applicant's invention to generate the listing of available treatment regimens based on the patient information and the knowledge base, since the knowledge base is where the plurality of different therapeutic treatment regimens for the disease is stored.

3. Claims 24-27 and 29-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-27 and 29-44 of U.S. Patent No. 6,081,786. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the limitations of claims 24-27 and 29-46 in the instant application are claimed in the patent, with the exception of selection of a therapeutic treatment regimen for a patient with a chronic known disease, providing patient information including prior therapeutic treatment regimen information for the chronic known disease or medical condition, and generating a listing of available therapeutic treatment regimens for the chronic known disease or medical condition based on the patient information and the first knowledge base. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention that the method could be applied to chronic diseases as well as any other type of medical condition where therapeutic treatments are applied to treat the symptoms. Also, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to include prior therapeutic treatment regimen information for the patient in order to understand the history of the patient so that changes in the regimen can be proposed that would potentially improve the health of the patient, especially if the prior treatment regimen has not been successful. This is a practice that has been typically performed by most physicians for many years. Furthermore, it would also have been obvious to one of ordinary skill in the art at the time of applicant's invention to generate the listing of available treatment regimens based on the patient information and the knowledge base, since the knowledge base is where the plurality of different therapeutic treatment regimens for the disease is stored.

4. Claims 47-50 and 52-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 45-48 and 50-66 of U.S. Patent No. 6,081,786.

Although the conflicting claims are not identical, they are not patentably distinct from each other because all the limitations of claims 47-50 and 52-69 in the instant application are claimed in the patent, with the exception of selection of a therapeutic treatment regimen for a patient with a chronic known disease, providing patient information including prior therapeutic treatment regimen information for the chronic known disease or medical condition, and generating a listing of available therapeutic treatment regimens for the chronic known disease or medical condition based on the patient information and the first knowledge base. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention that the method could be applied to chronic diseases as well as any other type of medical condition where therapeutic treatments are applied to treat the symptoms. Also, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to include prior therapeutic treatment regimen information for the patient in order to understand the history of the patient so that changes in the regimen can be proposed that would potentially improve the health of the patient, especially if the prior treatment regimen has not been successful. This is a practice that has been typically performed by most physicians for many years. Furthermore, it would also have been obvious to one of ordinary skill in the art at the time of applicant's invention to generate the listing of available treatment regimens based on the patient information and the knowledge base, since the knowledge base is where the plurality of different therapeutic treatment regimens for the disease is stored.

Allowable Subject Matter

5. Claims 1-4, 6-27, 29-50 and 52-69 are allowable over the prior art of record.

6. The following is a statement of reasons for the indication of allowable subject matter:

As per independent claim 1, the closest prior art of record (U.S. Patent No. 5,517,405 to McAndrew; "Application of an Expert System in the Management of HIV-Infected Patients" by Pazzani et al, or "A Computer-Assisted Management Program for Antibiotics and Other Antiinfective Agents" by Evans et al) taken either individually or in combination with other prior art of record fails to teach or suggest a method for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition, the method comprising providing patient information to a computing device

specifically comprising the three distinct knowledge bases as recited and generating in a computing device a listing of available therapeutic treatment regimens based on the patient information and the first knowledge base; and generating advisory information for one or more therapeutic treatment regimens in the listing based on the patient information and expert rules. Claims 2-4 and 6-23 are dependent upon claim 1 and thus have all the limitations of claim 1 and are allowable for that reason.

As per independent claim 24, the closest prior art of record (U.S. Patent No. 5,517,405 to McAndrew; "Application of an Expert System in the Management of HIV-Infected Patients" by Pazzani et al, or "A Computer-Assisted Management Program for Antibiotics and Other Antiinfective Agents" by Evans et al) taken either individually or in combination with other prior art of record fails to teach or suggest a system for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition, the system comprising providing patient information to a computing device specifically comprising the three distinct knowledge bases as recited and generating in a computing device a listing of available therapeutic treatment regimens based on the patient information and the first knowledge base; and generating advisory information for one or more therapeutic treatment regimens in the listing based on the patient information and expert rules. Claims 25-27 and 29-46 are dependent upon claim 24 and thus have all the limitations of claim 24 and are allowable for that reason.

As per independent claim 47, the closest prior art of record (U.S. Patent No. 5,517,405 to McAndrew; "Application of an Expert System in the Management of HIV-Infected Patients" by Pazzani et al, or "A Computer-Assisted Management Program for Antibiotics and Other Antiinfective Agents" by Evans et al) taken either individually or in combination with other prior art of record fails to teach or suggest a computer program product for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition, the computer program product comprising a computer usable storage medium having computer readable program code means embodied in the medium for providing patient information and for generating the three distinct knowledge bases as recited and generating a listing of available therapeutic treatment regimens based on the patient information and the first knowledge base; and generating advisory information for one or more therapeutic treatment

regimens in the listing based on the patient information and expert rules. Claims 48-50 and 52-69 are dependent upon claim 47 and thus have all the limitations of claim 47 and are allowable for that reason.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Dormond et al discloses an expert system which provides one or more suggested treatments for a patient.
- Brill et al discloses a system including knowledge bases to determine medications which may be used to relieve symptoms of injuries and illnesses covered by the knowledge base
- Chirico discloses an expert system with a plurality of independent knowledge bases
- Sillen et al discloses a method and system for giving patients individualized, situation dependent medication advice
- Brynjestad discloses a knowledge based expert interactive system for facilitating the diagnosis and treatment of acute and chronic pain
- Teagarden et al disclose an interactive computer assisted method for analyzing a patient who needs one or more medications and recommends changes to medications
- Jacobs et al disclose a system including a knowledge base for screening medical decisions and intended courses of action regarding a patient
- LaPointe et al [WO 97/29447] disclose a method for selecting medical diagnostic tests using neural network applications and knowledge bases
- Merz, Beverly discloses diagnostic expert systems used in the medical field to monitor treatment for medical conditions and provides advice on the proposed treatment regimen
- Molino et al disclose a knowledge based system for assisting physicians in patient management including therapeutic decisions and the prediction and treatment of side effects and complications
- Johnson, Kevin B. discloses a protocol based computer system used in medicine that is designed to serve as a data collection and management advice system for patients with oncologic diagnosis and

generates a treatment recommendation. Also discloses is a system for helping to manage patients infected with HIV.

- Ruffin, Marshall discloses a therapeutic decision support system that focuses on selection and prescription of medications checking for drug-drug interactions and optimal dosages
- Pazzani et al disclose the application of an expert system in the management of HIV-infected patients
- Walton et al disclose a computer support system including a knowledge base used to analyze patient data and generate suggestions for treatment
- Evans et al disclose a computer-assisted management program for antibiotics and other antiinfective agents

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Hayes whose telephone number is (703)306-5447. The examiner can normally be reached Monday through Friday from 5:30 to 3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Voeltz, can be reached on (703) 305-9714.

The Fax phone number for the **UNOFFICIAL FAX** for the organization where this application or proceeding is assigned is (703) 305-0040 (for informal or draft communications, please label "PROPOSED" or "DRAFT").

The Fax phone number for the **OFFICIAL FAX** for the organization where this application or proceeding is assigned is (703) 308-9051 or 9052 (for formal communications intended for entry).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3900.

jwh

30 June 2000

EMANUEL TODD VOELTZ
SUPERVISORY PATENT EXAMINER
GROUP 2700